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**UNITED STATES DISTRICT COURT
 FOR THE NORTHERN DISTRICT OF CALIFORNIA
 SAN FRANCISCO DIVISION**

<p>IN RE: BABY FOOD PRODUCTS LIABILITY LITIGATION</p>	<p>Case No. 24-MD-3101-JSC MDL 3101</p>
<p>This Document Relates To:</p> <p>Nicholaus Zimmerman, on Behalf of C.Z., A MINOR,</p> <p style="text-align: center;"><i>Plaintiff,</i></p> <p>v.</p> <p>Campbell Soup Company, Gerber Products Company, Nestlé Holdings, Inc., Nestlé S.A., Plum, PBC, Sun-Maid Growers of California, and DOES 1 through 10 inclusive</p> <p style="text-align: center;"><i>Defendants.</i></p>	<p>Hon. Jacqueline Scott Corley</p> <p>COMPLAINT AND JURY DEMAND</p> <p>Case no.:</p>

INTRODUCTION

1. Defendants *knowingly* sold baby food products contaminated with lead, arsenic,

1 mercury, cadmium, and aluminum (collectively “Toxic Heavy Metals”). They did this knowing
2 that Toxic Heavy Metals, when consumed by babies, are known to cause brain damage and
3 neurodevelopmental harm. Thus, to the extent Defendants sold baby food that contained
4 detectable amounts of Toxic Heavy Metals (collectively “Contaminated Baby Food”) those
5 products were defective in their manufacture, design, and labeling. Babies are the most
6 vulnerable segment of the population, and they rely on that food for healthy neurodevelopment.
7 Defendants justify this callous disregard for the welfare of babies because, until recently, there
8 were no regulations governing the presence of Toxic Heavy Metals in baby foods—and,
9 because there were no regulations, they were free to do as they pleased.

10 2. This lawsuit aims to stop Defendants from poisoning infants with Contaminated
11 Baby Food. Baby food *should* be safe. It should *not* be contaminated with Toxic Heavy
12 Metals. Period. By sourcing ingredients from farms that have non-detectable levels of heavy
13 metal (using sufficiently sensitive testing), avoiding certain ingredients all together, and
14 systematically testing and screening finished products for Toxic Heavy Metals *before* the foods
15 are released for consumption, these Defendants would be able to provide baby food products
16 free of detectable levels of Toxic Heavy Metals. And, if some levels are truly unavoidable, or if
17 Defendants believe the identified levels are safe, then, at the very least, Defendants must warn
18 parents/guardians/caregivers about the presence of these Toxic Heavy Metals so they can make
19 informed decisions about what they are feeding their baby. Anything short of proper design,
20 manufacture, and warning, is unacceptable—especially for an industry that touts itself as
21 providing the most important sources of neurodevelopment for the most vulnerable population
22 of society.

23 3. Plaintiff, here, lives with brain injuries and neurodevelopmental harm caused by
24 exposure to the Defendants’ Contaminated Baby Food, which has manifested in diagnoses of
25 autism spectrum disorder (“ASD”). Plaintiff’s parents were never warned that the Defendants’
26 food contained Toxic Heavy Metals and, thus, were never able to make an informed decision
27 about whether to feed their babies Defendants Contaminated Baby Foods. The consequences
28 are stark—there is an unprecedented epidemic of ASD and ADHD spreading throughout the

1 American population, driven, in part, by the systematic neurodevelopmental poisoning of
2 infants from these Defendants' Contaminated Baby Foods.

3 4. This case seeks to hold the Defendants accountable for their reprehensible
4 conduct by compensating Plaintiff who was harmed by the Defendants' Contaminated Baby
5 Foods, and ensure each Defendant is punished to deter such conduct in the future.

6 **PARTIES**

7 **I. Plaintiff**

8 5. Plaintiff is a child who lives with brain injuries and neurodevelopmental harm
9 caused by exposure to the Defendants' Contaminated Baby Food, which has manifested in a
10 diagnosis of ASD.

11 6. Plaintiff consumed baby foods manufactured by Gerber Products Company and
12 Plum, PBC.

13 7. Plaintiff consumed these baby foods from approximately March 1, 2020 to
14 approximately September 20, 2020.

15 8. Plaintiff alleges that as a direct and proximate result of Plaintiff's exposure to
16 Toxic Heavy Metals from consumption of Defendants' Contaminated Baby Foods, they
17 suffered significant harm, conscious pain and suffering, physical injury and bodily impairment
18 including, but not limited to, brain injury manifesting as the neurodevelopmental disorder ASD,
19 other permanent physical deficits, permanent bodily impairment, and other *sequelae*. Plaintiff
20 was diagnosed on or around June 17, 2022. Plaintiff's injuries required medical intervention to
21 address the adverse neurological effects and damage caused by exposure to Toxic Heavy Metals
22 in Defendants' Contaminated Baby Foods. Additionally, Plaintiff has suffered severe mental
23 and physical pain, including but not limited to, pain, mental suffering, loss of enjoyment of life,
24 disfigurement, physical impairment, inconvenience, grief, anxiety, humiliation, and emotional
25 distress and has and will sustain such injuries, along with economic loss due to medical
26 expenses and living-related expenses as a result of lifestyle changes, into the future, as
27 determined by the Trier of Fact.

28 9. The product warnings for the Contaminated Baby Foods in effect during the time

1 period Plaintiff consumed the Contaminated Baby Foods were non-existent, vague, incomplete
 2 and/or otherwise inadequate, both substantively and graphically, to alert consumers to the
 3 presence of Toxic Heavy Metals in the Contaminated Baby Foods and/or the potentially severe
 4 health risks associated with Toxic Heavy Metal exposure in babies. Thus, each Defendant did
 5 not provide adequate warnings to consumers including Plaintiff, their parents, and the general
 6 public about the presence of Toxic Heavy Metals in the Contaminated Baby Foods consumed
 7 by Plaintiff and the potential risk of the serious adverse events associated with Toxic Heavy
 8 Metal exposure in infancy.

9 10. Had Plaintiff or their parents been adequately warned by the Defendants of the
 10 potential for exposure to Toxic Heavy Metals from consumption of Defendants' Baby Foods,
 11 and/or the potential for such exposure to result in harm, Plaintiff, or their parents would not
 12 have purchased, used and/or consumed Contaminated Baby Foods or would have taken other
 13 steps to potentially mitigate the harm caused by exposing a baby to Toxic Heavy Metals.

14 **II. Defendants**

15 11. The following are the Defendants listed in this Complaint. In alphabetical order:

- 16 1. Campbell Soup Company ("Campbell")
- 17 2. Gerber Products Company ("Gerber")
- 18 3. Nestlé Holdings, Inc. ("NHI")
- 19 4. Nestlé S.A. ("Nestlé")
- 20 5. Plum, PBC ("Plum")
- 21 6. Sun-Maid Growers of California ("Sun-Maid")

22 12. Defendant Gerber Products Company ("Gerber") is a citizen of Michigan and
 23 Virginia with its principal place of business located at 1812 N. Moore Street, Arlington,
 24 Virginia 22209. Gerber sells Baby Foods under the brand name Gerber. Gerber organizes its
 25 products into broad categories of "formula," "baby cereal," "baby food," "snacks," "meals &
 26 sides," "beverages," and "organic." At all relevant times, Gerber has conducted business and
 27 derived substantial revenue from its manufacturing, labeling, advertising, distributing, selling,
 28 and marketing of baby foods. Gerber is a wholly owned subsidiary of and is directly controlled

1 by Nestlé Holdings, Inc.

2 13. Defendant Nestlé Holdings, Inc. (“NHI”) is a citizen of Delaware and Virginia
3 with its principal place of business located at 1812 N. Moore Street, Arlington, Virginia 22209.
4 According to its December 2023 annual report, “NHI is the holding company for Nestlé S.A.’s
5 principal operating subsidiaries in the United States, which include, among others, Nestlé USA,
6 Inc., Nestlé Purina Petcare Company, and Gerber Products Company.” NHI is a wholly owned
7 subsidiary of Nestlé S.A. (“Nestlé”). Thus, NHI is the holding company for Nestlé that directly
8 controls and operates Gerber—as noted by the sharing of the same address. Indeed, nearly
9 every safety specialist that oversees the heavy metal content of Gerber baby foods, working
10 currently in the internal project “Metallica,” are employed directly by NHI and/or Nestlé S.A.
11 At all relevant times, NHI conducted business and derived substantial revenue through Gerber
12 by manufacturing, advertising, distributing, selling, and marketing baby foods within the
13 judicial districts involved in this litigation.

14 14. Defendant Nestlé is a citizen of Switzerland, with its principal place of business
15 located at Avenue Nestlé 55, 1800 Vevey, Switzerland. Nestlé is a global food and beverage
16 company with more than 2,000 brands. Nestlé sells baby foods under its subsidiary, Gerber,
17 which it directly controls through its wholly owned subsidiary NHI. Employees and scientists
18 at Nestlé trained and set safety standards at Gerber. Indeed, in discovery ongoing in other
19 litigation, Gerber specifically identified scientists at Nestlé to testify on behalf of Gerber
20 regarding the safety of Gerber’s baby food products. Nestlé, thus, has been directly involved in
21 the tortious conduct in the United States and its various states that gives rise to these lawsuits.
22 At all relevant times, Nestlé conducted business and derived substantial revenue through Gerber
23 and/or NHI by manufacturing, advertising, distributing, selling, and marketing baby foods
24 within the judicial districts involved in this litigation.

25 15. The relationship between Gerber, NHI, and Nestlé was formed in 2007. Prior to
26 that, starting in 1994, Gerber was owned and operated by Novartis, one of the largest
27 pharmaceutical companies in the world. However, in 2007, Gerber was sold to Nestlé for \$5.5
28 billion.

1 16. For the purposes of this Complaint, unless specifically stated otherwise, NHI and
2 Nestlé shall be collectively referred to as “Nestlé.” Further, allegations related to Gerber apply
3 equally to NHI and Nestlé, as each Defendant exercised authority and control over the sale,
4 manufacture, and distribution of Gerber’s Contaminated Baby Foods at issue in this MDL.

5 17. Defendant Plum, PBC (“Plum”) is a citizen of Delaware and California with its
6 principal place of business located at 6795 N. Palm Ave., 2nd Floor, Fresno, California 93704.
7 Plum sells Baby Foods under the brand name “Plum Organics” and has done so since 2007.
8 Starting in 2013, and until May 3, 2021, Plum was directly controlled and owned by Defendant
9 Campbell. Plum’s products are divided into groups according to the targeted infant or toddler
10 age and/or type of food product. For example, there are five groups designated for the youngest
11 infants: Stage 1 (4+ months old), Stage 2 (6+ months old), Stage 3 (6+ months old), “Super
12 Puffs,” and “Little Teethers.” At all relevant times, Plum has conducted business and derived
13 substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of
14 baby foods within this judicial district and throughout the United States.

15 18. Defendant Campbell Soup Company (“Campbell”) is a Citizen of New Jersey
16 with its principal place of business located at One Campbell Pl., Camden, New Jersey 08103.
17 Campbell sells food and beverages and was the parent company of Plum until May 3, 2021,
18 wherein Campbell sold Plum to Defendant Sun-Maid, a few months after the first heavy metal
19 lawsuits were filed. Campbell sold baby food under the brand name Plum Organics through
20 Plum. Indeed, many of the scientists and researchers that monitored the safety of Toxic Heavy
21 Metals in Plum’s baby foods were directly employed by Campbell or were directly controlled
22 and trained by Campbell agents and employees. For example, it was Campbell’s attorneys that
23 responded to Congressional inquiries about heavy metals in Plum baby foods in 2019.
24 Campbell exercised control over Plum’s baby food selling in the United States until May 3,
25 2021. At all relevant times, Campbell conducted business and derived substantial revenues
26 from its manufacturing, advertising, distributing, selling, and marketing of baby foods within
27 this judicial district and throughout the United States.

28 19. Defendant Sun-Maid Growers of California (“Sun-Maid”) is a citizen of

California with its principal place of business located at 6795 N. Palm Ave., Fresno, California 93711. Sun-Maid sold baby food through Plum, starting on May 3, 2021. Sun-Maid acquired Plum from Campbell on May 3, 2021. Sun-Maid has since been directly involved with all aspects of the safety and testing of Plum's baby food products. For example, metal testing is paid for directly and sent directly to Sun-Maid's scientists and executives, not directly to Plum. All major executive functions related to Plum's operation were specifically transitioned from Campbell to Sun-Maid. Like Campbell, Sun-Maid has exercised and continues to exercise direct control over the manufacture, sale, and distribution of all Plum baby foods since May 3, 2021. At all relevant times, Sun-Maid conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

20. For the purposes of this Complaint, allegations related to Plum between 2013 and May 3, 2021 apply equally to Campbell, unless otherwise specified, and allegations related to Plum after May 3, 2021 apply equally to Sun-Maid, as each Defendant exercised authority and control over the sale, manufacture, and distribution of Plum's Contaminated Baby Foods at issue in this MDL.

JURISDICTION AND VENUE

21. Plaintiff(s) file this Complaint pursuant to CMO No. 5, and are to be bound by the rights, protections, and privileges, and obligations of that CMO and other Order of the Court. Further, in accordance with CMO No. 5, Plaintiff(s) hereby designate the United States District Court for the Northern District of Indiana as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this selection based upon one (or more) of the following factors (check the appropriate box(es))

☒ Plaintiff currently resides in Valparaiso, Indiana.

☒ Plaintiff purchased and consumed Defendant(s) products in Indiana.

☐ The Original Venue is a judicial district in which Defendant _____ resides, and all Defendants are residents of the State in which the district is located (28 U.S.C. 1391(b)(1)).

1 X The Original Venue is a judicial district in which a substantial part of the events or
2 omissions giving rise to the claim occurred, specially (28 U.S.C. 1391 (b)(2)):

3 _____ There is no district in which an action may otherwise be brought under 28 U.S.C.
4 1391, and the Original Venue is a judicial district in which Defendant _____ is subject
5 to the Court's personal jurisdiction with respect to this action (28 U.S.C. 1391 (b)(3)).

6 _____ Other reason (please explain): _____
7

8 22. As an MDL transferee court, this Court has subject matter and personal
9 jurisdiction to the same extent as the respective transferee courts do. In general, federal courts
10 have subject matter jurisdiction over this action under 28 U.S.C. § 1332(d) because Plaintiff is a
11 citizen of a state other than states where Defendants are citizens. In addition, Plaintiff seeks
12 damages in excess of \$75,000, exclusive of interest and costs.

13 23. This Court has personal jurisdiction over Defendants because their significant
14 contacts related to this litigation in each State make personal jurisdiction proper over any of
15 them.

16 24. In particular, this Court has personal jurisdiction over Defendants for cases filed
17 in this District insofar as Defendants are authorized and licensed to conduct business in the
18 State of California, maintain and carry on systematic and continuous contacts in this judicial
19 district, regularly transact business within this judicial district, and regularly avail themselves of
20 the benefits of this judicial district.

21 25. Additionally, Defendants caused tortious injury by acts and omissions in this
22 judicial district and caused tortious injury in this district by acts and omissions outside this
23 district while regularly doing and soliciting business, engaging in a persistent course of conduct,
24 and deriving substantial revenue from goods used or consumed and services rendered in this
25 judicial district.

26 26. Nestlé and NHI are subject to personal jurisdiction in the relevant judicial
27 districts insofar as they are authorized and licensed to conduct business in their respective
28 states. Additionally, these Defendants maintain and carry on systematic and continuous

1 contacts in these judicial districts, regularly transact business within these districts, and
2 regularly avail themselves of the benefits of these districts. These Defendants caused tortious
3 injury by acts and omissions in these judicial districts and by acts and omissions outside these
4 districts while regularly doing and soliciting business, engaging in a persistent course of
5 conduct, and deriving substantial revenue from goods used or consumed and services rendered
6 in these districts.

7 **FACTUAL ALLEGATIONS**

8 **I. Rising Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods**

9 27. In October 2019, an alliance of nonprofit organizations, scientists and donors
10 named “Happy Babies Bright Futures” (“HBBF”), dedicated to designing and implementing
11 “outcomes-based programs to measurably reduce babies’ exposures to toxic chemicals,”
12 published a report investigating the presence of Toxic Heavy Metals in baby foods. The HBBF
13 Report tested 168 different baby foods sold on the U.S. market and concluded that “[n]inety-
14 five percent of baby foods tested were contaminated with one or more of four toxic heavy
15 metals—arsenic, lead, cadmium and mercury. All but nine of 168 baby foods contained at least
16 one metal; most contained more than one.” Specifically, the HBBF report identified “puffs and
17 other snacks made with rice flour,” “[t]eething biscuits and rice rusks,” “infant rice cereal,”
18 “apple, pear, grape and other fruit juices,” and “carrots and sweet potatoes” manufactured by
19 the Defendants as particularly high in Toxic Heavy Metals.

20 28. The results of the HBBF report were consistent with that of the U.S. Food and
21 Drug Administration (“FDA”) which had, in 2017, detected one or more of the four Toxic
22 Heavy Metals in 33 of 39 types of baby food tested. However, the HBBF reported that “[f]or
23 88 percent of baby foods tested by HBBF—148 of 168 baby foods—FDA has failed to set
24 enforceable limits or issue guidance on maximum safe amounts.” The HBBF’s findings were
25 by no means an outlier. Eight months prior to publication of the HBBF report, a study
26 conducted by scientists at the University of Miami and the Clean Label Project “examined
27 lead...concentrations in a large convenience sample of US baby foods.” The study detected
28 lead in 37% of samples.

29. Moreover, earlier in 2017, HBBF commissioned a study to evaluate the presence of arsenic in infant rice cereal products sold in the U.S., and the potential risks to children's neurodevelopment posed by contamination levels. The findings were concerning. The authors concluded that "exposures to arsenic from infant rice cereal approach or exceed existing health-based limits for arsenic levels...leaving little room for additional exposures from other dietary sources, such as snacks, apple juice, and drinking water...Our analyses of arsenic exposures from infant rice cereal during the first year of life suggest that these exposures are not insignificant, and may place infants at risk for adverse health effects."

II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods Manufactured and/or Sold by Defendants, Sparking National Outrage

30. On February 4, 2021, and September 29, 2021, respectively, the U.S. House of Representatives' Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, published two reports detailing its findings that Toxic Heavy Metals—including lead, arsenic, mercury, and cadmium—were present in "significant levels" in numerous commercial Baby Food Products. Four companies—Hain, Gerber (Nestlé), Nurture (Danone), and Beech-Nut—produced internal testing policies, test results for ingredients and finished products, and documentation about what the companies did with ingredients and/or finished products that exceeded their internal testing limits. Three companies—Plum (Campbell), Walmart, and Sprout—initially refused to cooperate.

31. Congress reported that the data submitted by the companies unequivocally revealed that a substantial number of Defendants' finished products and/or ingredients used to manufacture the Baby Foods are tainted with Toxic Heavy Metals, namely lead, arsenic, mercury, and cadmium. And, where the Defendants did set internal limits for the amount of metals they allowed in their foods, Defendants routinely flouted their own limits and sold foods that consistently tested above their limits. Congress found the following:

32. **Gerber.** Gerber along with Nestlé used high-arsenic ingredients, using 67 batches of rice flour that had tested over 90 ppb inorganic arsenic. Nestlé and Gerber used ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20

1 ppb lead. Nestlé and Gerber rarely test for mercury in their baby foods. In the September 2021
2 follow-up Congressional report, it was revealed that Nestlé and Gerber’s rice cereal tested up to
3 116 ppb inorganic arsenic, and their average rice cereal product contained 87.43 ppb inorganic
4 arsenic, which is even higher than the amount contained in Beech-Nut’s average rice cereal
5 product. While Beech-Nut recalled some of its products and completely discontinued sales of
6 its rice cereal, Nestlé and Gerber have taken no such actions to protect children.

7 33. **Plum.** Plum, along with Campbell, refused to cooperate with the Congressional
8 investigation. Instead of producing any substantive information, Campbell provided Congress
9 with a self-serving spreadsheet declaring that every one of its products sold through Plum
10 “meets criteria”, while declining to state what those criteria were. Disturbingly, Campbell
11 admitted that, for mercury (a powerful neurotoxin), Campbell and Plum have *no criterion*
12 whatsoever, stating: “No specific threshold established because no high-risk ingredients are
13 used.” However, despite Campbell and Plum having no mercury threshold, Campbell and Plum
14 still marked every food as “meets criteria” for mercury. Congress noted that “[t]his misleading
15 framing—of meeting criteria that do not exist—raises questions about what [Plum’s] other
16 thresholds actually are, and whether they exist.” This suspicion is confirmed by HBBF’s
17 independent testing which confirms the presence of Toxic Heavy Metals in Campbell and Plum
18 Baby Food, which found excess levels of lead, arsenic, and mercury in Campbell and Plum’s
19 Just Sweet Potato Organic Baby Foods; Just Peaches Organic Baby Food; Just Prune Organic
20 Baby Food; Pumpkin Banana Papaya Cardamom; Apple, Raisin & Quiona Organic Baby Food;
21 Little Teethers Organic Multigrain Teething Wafers-Banana with Pumpkin; and Mighty
22 Morning Bar-Blueberry Lemon-Tots. Furthermore, as discussed further below, based upon
23 information and belief, Plaintiff submits that Campbell and Plum’s pattern and practice of
24 failing to test ingredients, willingly flouting their own internal standards, and selling products
25 notwithstanding internal acknowledgement of their high metal content, follows that of the other
26 Defendants discussed in this Complaint, and discovery here will further flesh out the extent of
27 Campbell and Plum’s culpable conduct.

28 34. The metal concentrations discussed above and further below surpass the limits

1 allowed by U.S. regulatory agencies. There are no FDA final regulations governing the
2 presence of Toxic Heavy Metals in the majority of Baby Foods with the exception of 100 ppb
3 inorganic arsenic in infant rice cereal and proposed (not yet final) limits for lead in certain baby
4 food categories. To the extent such regulations exist, the quantities of Toxic Heavy Metals in
5 Defendants' Baby Foods exceed any permissible FDA levels. To be sure, the FDA has set the
6 maximum contaminant levels ("MCL") in bottled water at 10 ppb inorganic arsenic, 5 ppb lead,
7 and the EPA has capped the allowable level of mercury in drinking water at 2 ppb. However,
8 these limits were created in reference to *adult* exposure, not infants. Compared to these
9 thresholds, the test results of the Defendants' baby foods and their ingredients are multiple folds
10 greater than the permitted metal levels. Moreover, compounding these troubling findings, the
11 Defendants set internal limits for the presence of Toxic Heavy Metals in their foods that were,
12 themselves, dangerously high and then routinely failed to abide by those inadequate standards,
13 as discussed below.

14 35. As Congress observed, the Defendants have willfully sold—and continue to
15 sell—contaminated Baby Foods notwithstanding their full awareness of these unacceptably high
16 levels of Toxic Heavy Metals in their products.

17 **III. Defendants Engaged in a Pattern and Practice of Selling Contaminated Baby Foods** 18 **and Failed to Reduce Metal Levels**

19 36. Several factors drive the Toxic Heavy Metal contamination of Defendants' baby
20 foods, all of which are within Defendants' control.

21 37. *First*, at various times, all Defendants sourced ingredients that contained
22 elevated levels of Toxic Heavy Metals. These ingredients were then used to manufacture the
23 baby foods consumed by Plaintiff, thereby exposing Plaintiff to Toxic Heavy Metals that cause
24 brain damage and other neurodevelopmental harm. One way for Defendants to "deal" with this
25 issue involved relegating any testing of Toxic Heavy Metals to suppliers and co-manufacturers,
26 who were required to certify that Toxic Heavy Metals were below a certain threshold.
27 Defendants would audit those results, discover that the reported certifications were false or
28 inaccurate, and then take no action to stop the use of those ingredients or finished products.

1 38. *Second*, some Defendants implemented dangerously high internal limits
2 (“specifications” or “specs”) for the maximum level of Toxic Heavy Metals that Defendants
3 allowed in the baby foods. Such high limits—untethered to any consideration of the low levels
4 at which metals are capable of damaging babies’ brains—allowed Defendants to source and use
5 ingredients that contained elevated Toxic Heavy Metals to manufacture the baby foods
6 consumed by Plaintiff. In the highly competitive and lucrative baby food market, using
7 contaminated ingredients allows each Defendant to retain greater market share.

8 39. *Third*, some Defendants failed to implement *any* internal specifications for the
9 amount of Toxic Heavy Metals allowed in ingredients or finished baby foods. By simply not
10 looking at the issue, certain highly contaminated ingredients and finished products were allowed
11 to be used and sold to consumers. This would happen notwithstanding the Defendants’ specific
12 knowledge of the risk of Toxic Heavy Metals and their presence in ingredients and finished
13 products.

14 40. *Fourth*, Defendants did not routinely adhere to their own internal metal
15 specifications or standards, allowing contaminated ingredients and finished products to be
16 released as “exceptional releases” or other simpler terminology. This resulted in ingredients
17 being used and baby foods manufactured and sold that contained levels of Toxic Heavy Metals
18 far higher than what was internally set by Defendants. In other instances, Defendants would
19 test products that had been put on the market after-the-fact, learn about the products containing
20 extremely high levels of Toxic Heavy Metals, and then take no action to recall the product or
21 warn consumers about the issue.

22 41. *Fifth*, upon information and belief, Defendants’ manufacturing practices also
23 contributed to contamination. For example, the water used at some of the facilities where the
24 baby foods were manufactured contained Toxic Heavy Metals which, in turn, ended up in the
25 finished baby food product sold for consumption by babies.

26 42. **Gerber.** Gerber, NHI, and Nestlé tested ingredients and, occasionally, finished
27 products. However, while Gerber, NHI, and Nestlé were the only Defendants to test both
28 ingredients and finished products with any regularity, they set high heavy metal limits that

1 rendered their food unsafe. For baby foods generally, between 2012 and 2019, Gerber, NHI,
2 and Nestlé set a limit of 40 ppb for lead, 20 ppb for arsenic, and 10 ppb for mercury. For infant
3 rice cereal, between 2012 and 2017, Gerber, NHI, and Nestlé set a lead limit of 100 ppb, with a
4 “target” of 50 ppb in 2016 and 2017. Between 2018 and 2019, Gerber, NHI, and Nestlé set a
5 lead limit for 50 ppb. For arsenic in rice cereal, between 2012 and 2015, Gerber, NHI, and
6 Nestlé did not have a limit, merely a target of 100 ppb. Then, between 2016 and 2018, it set the
7 arsenic limit at 100 ppb. By 2019, Gerber, NHI, and Nestlé increased the arsenic limit to 130
8 ppb for cereals with 90% rice (and kept the limit at 100 ppb for other cereals). For snack foods,
9 Gerber, NHI, and Nestlé had a lead limit of 150 ppb between 2012 and 2014. It was reduced to
10 100 ppb in 2016 and 2017, and then went down to 50 ppb in 2018 and 2019. There was no limit
11 for arsenic in snack food prior 2016, just a “target” of 100 ppb. Then a 100-ppb arsenic limit
12 was set starting in 2016. For both infant cereal and snacks, Gerber, NHI, and Nestlé imposed a
13 30-ppb limit for mercury in infant cereal between 2012 and 2016, and reduced it to 10 ppb from
14 2017 onward. With these exceptionally high limits, Gerber, NHI, and Nestlé sold baby foods
15 that were dangerous for infant consumption. They did this knowingly.

16 43. Gerber, NHI, and Nestlé would also audit and re-test Toxic Heavy Metal results
17 submitted by suppliers, and find that the certification from suppliers were incorrect or false.
18 Gerber, NHI, and Nestlé would nonetheless use the certified results and release products despite
19 the ingredients not meeting specifications or being safe for infant consumption.

20 44. Gerber, NHI, and Nestlé often used high-arsenic ingredients, for example, using
21 67 batches of rice flour that had tested over 90 ppb inorganic arsenic. Furthermore, Gerber,
22 NHI, and Nestlé regularly sold baby food products testing over 100 ppb arsenic, at times
23 reaching 116 ppb, and their average rice cereal product contained 87.43 ppb inorganic arsenic.
24 Indeed, this is why Congress noted that “Gerber’s organic rice cereal is dangerous...” In other
25 instances, Gerber permitted as much as 300 ppb of arsenic in the rice flour ingredient used to
26 manufacture its U.S. baby foods, notwithstanding the fact that Gerber often implemented
27 stricter standards for baby foods sold in other countries.

28 45. Gerber’s baby foods are also contaminated with elevated levels of lead. Gerber,

1 NHI, and Nestlé used ingredients that tested as high as 48 ppb lead and used many ingredients
2 containing over 20 ppb lead. Furthermore, Gerber, NHI, and Nestlé sold baby food products
3 testing at and/or above 50 ppb of lead. Indeed, Gerber, NHI, and Nestlé have historically
4 permitted as much as 150 ppb lead in their baby food products. Although Gerber, NHI, and
5 Nestlé were fully aware that it was very feasible to source lower-lead ingredients, they
6 proceeded to use high-lead ingredients in their baby foods. Gerber, NHI, and Nestlé rarely test
7 for mercury in their baby foods. This is notwithstanding the fact that mercury is known to
8 contaminate ingredients such as rice and poses a severe risk to babies' brain development.

9 46. The February 4, 2021 Congressional Report found Gerber carrots tested for
10 cadmium at levels above 5 ppb, with some containing more than 87 ppb of cadmium. These are
11 exceptionally high levels.

12 47. Moreover, compounding these troubling findings, Gerber, NHI, and Nestlé
13 historically only tested certain ingredients of its baby food products and only occasionally tested
14 the finished products consumed by babies. It was not until recently that Gerber, NHI, and
15 Nestlé started to implement finished product testing on a more regular basis.

16 48. Gerber, NHI, and Nestlé have known since at least the 1990s that inorganic
17 arsenic was neurotoxic and caused developmental issues. Despite this knowledge, in 2012,
18 when Gerber's infant rice cereal was on the front page of a Consumer Report article on arsenic,
19 a Gerber spokesperson told the public that arsenic in baby food posed no health risk.

20 49. **Plum.** Plum was founded in 2007 and has sold a wide variety of baby food
21 products under the name Plum Organics since that time. Plum was owned and controlled by
22 Campbell from roughly 2013 until roughly May 2021 when Plum was sold to Sun-Maid.

23 50. Despite Plum's public facing statements that "little ones deserve the very best
24 food from the very first bite" and despite understanding that environmental toxins like heavy
25 metals can cause neurodevelopmental disorders in children, Plum and Campbell/Sun-Maid did
26 very little to ensure that the Plum baby food products marketed for consumption by children are
27 not contaminated with dangerous levels of heavy metals. For example, though Plum and
28 Campbell/Sun-Maid knew that the heavy metal contents of the ingredients used in its products

1 varied by growing region and supplier, they did not undertake an effort to source ingredients
2 with the lowest amount of heavy metals available. And, despite knowing that certain
3 ingredients carry a higher risk for heavy metal contamination, Plum and Campbell/Sun-Maid
4 did not reformulate their products to ensure that they were being made with the lowest
5 achievable amount of heavy metals.

6 51. Plum and Campbell failed to set limits on the amount of heavy metals that could
7 be present in Plum's finished baby food products. From 2007 to at least April 2021, they did
8 not set *any* limits for the amount of lead, arsenic, mercury, cadmium, or aluminum that their
9 finished products could contain.

10 52. Plum and Campbell also failed to set limits on the amount of heavy metals that
11 could be present in the ingredients used in Plum's baby food products. Prior to 2016, they did
12 not set limits for the amount of heavy metals that could be present in the ingredients used in
13 Plum products. When Plum and Campbell did begin to implement heavy metal limits for Plum
14 ingredients (in or around 2017), it did so only for lead, arsenic, and cadmium. As of April
15 2021, Plum and Campbell still had no limits for the amount of mercury and aluminum that
16 could be in the ingredients used in their baby food products.

17 53. When Plum did set some heavy metal limits (for lead and arsenic for ingredients
18 only) it set those limits several times in excess of what was achievable for most ingredients.
19 For example, despite certain fruits and vegetables normally containing less than 5 ppb lead or
20 arsenic, Plum set the heavy metal limits for all Plum ingredients for lead and arsenic at 100 ppb.
21 And, even still, despite setting these limits dangerously high, Plum and Campbell/Sun-Maid still
22 utilized ingredients that tested in excess of those limits.

23 54. Plum and Campbell/Sun-Maid also conducted very little oversight of their co-
24 manufacturers to ensure that the heavy metal limits for ingredients used in Plum products were
25 adhered to. For example, prior to 2017, Plum and Campbell did not require the ingredient
26 suppliers they contracted with to submit heavy metal testing data but instead relied on supplier
27 assurances that the ingredients did not contain heavy metals and/or complied with all
28 government regulations regarding heavy metals. When Plum and Campbell/Sun-Maid did

1 begin to require testing on some of the ingredients used in its products for lead and arsenic,
2 those efforts were scattershot and did not extend to all lots of all ingredients used in Plum baby
3 food products. Where verification testing was conducted on ingredients, it was often done in an
4 unaccredited lab.

5 55. Despite not having a comprehensive ingredient testing program to ensure that
6 Plum food marketed for babies was not contaminated with Toxic Heavy Metals, Plum and
7 Campbell/Sun-Maid also did not conduct heavy metal testing on Plum products prior to sale.
8 Plum only first conducted finished product testing in the wake of public reports that exposed
9 Plum baby food products as being contaminated with dangerous levels of heavy metals. Upon
10 information and belief, no rigorous heavy metal testing program on ingredients and finished
11 product was ever implemented and Plum and Campbell/Sun-Maid continued and continue to
12 sell baby food contaminated with elevated levels of heavy metals without first testing to ensure
13 their safety.

14 **IV. Defendants Abandon Efforts to Reduce Metal Levels in Baby Foods**

15 56. In 2019, as concerns grew over contamination of certain baby foods on the U.S.
16 market, a consortium of the Defendants comprised of Plum/Campbell and Gerber, as well as
17 certain interested third party groups such as the Environmental Defense Fund (“EDF”) and
18 HBBF, were formed with the intention “of reducing heavy metals in young children’s food.”

19 57. The consortium was named the Baby Food Council (“BFC”). The BFC involved
20 the sharing of common testing data on the levels of metal contamination of Defendants’ baby
21 foods, a grant to Cornell University to further study the issue, and a proposed “voluntary Baby
22 Food Standard to limit the amounts of heavy metals in baby food.” The BFC specifically
23 recognized the risk of neurodevelopmental harm caused by Toxic Heavy Metals to the
24 developing brain of infants and that there were no safe levels of exposure.

25 58. The Baby Food Standard “would have provided companies with a common
26 framework for progressively reducing contaminants by regularly testing products and
27 improving management practices, and for being transparent with consumers about the safety of
28 their products.”

59. After several years of negotiations and discussions, including a proposed system for testing, the EDF and HBBF proposed voluntary limits of 1 ppb for lead. The baby food companies, however, rejected the proposal outright. Participation in the BFC was little more than a façade—they had no intention of self-regulating their products as it related to Toxic Heavy Metals.

60. This led EDF and HBBF to leave the BFC in protest in 2021. They explained their departure publicly, noting that Defendants “all decided to backpedal on this project—even though the standard was designed to protect babies’ brain development” and provide adequate notice to consumers regarding the presence of Toxic Heavy Metals on Baby Food labeling.

EDF explained:

EDF cofounded the Council because we believed there was a shared commitment to reduce levels of lead, arsenic and cadmium in baby food products to better protect children’s developing brains from these toxins ... Unfortunately, the companies chose to cease the Council’s development of a voluntary Baby Food Standard that it had begun in late 2020. The Standard would have provided companies with a common framework for progressively reducing contaminants by regularly testing products and improving management practices, and for being transparent with consumers about the safety of their products. Negotiations failed to provide an alternative approach that EDF felt was sufficient to drive down levels of lead, arsenic and cadmium in baby food.”

61. HBBF explained:

Healthy Babies Bright Futures is focused on tangibly reducing neurotoxic exposures to babies. The baby food companies’ refusal to jointly set limits for heavy metals in baby food has shown that the Council will no longer be the powerful mechanism for this important work that the initial plans had promised. The baby food companies’ decision to stop progress on a voluntary standard for heavy metals in baby food is a disappointment ... What started as dedication has turned into delay and intention has become inaction. So HBBF has decided to put our effort into other initiatives that will move the needle on this important issue.

62. In short, the Defendants opted to continue “self-regulating,” the same self-regulation which exposed—and continued to expose—Plaintiff to Toxic Heavy Metals in Defendants’ baby foods.

V. The Dangers of Toxic Heavy Metals and Metal Exposure Through Consumption of Baby Foods

63. According to the World Health Organization (“WHO”), Toxic Heavy Metals, specifically lead, arsenic, mercury, and cadmium pose a “major public health concern” for

1 children. The Occupational Safety and Health Administration (“OSHA”) has warned that these
2 metals “may build up in biological systems and become a significant health hazard.” Indeed,
3 the Department of Health and Human Services’ Agency for Toxic Substances and Disease
4 Registry (“ATSDR”) ranks arsenic as number *one* among substances present in the environment
5 that pose the most significant potential threat to human health, followed by lead (second),
6 mercury (third), and cadmium (seventh).

7 64. The threat presented by Toxic Heavy Metals to children’s health is widely shared
8 by the global regulatory and scientific community. For example, the FDA has set an Interim
9 Reference Level (“IRL”) of 2.2 micrograms/day for lead exposure through baby food products.
10 That is the amount of lead exposure at or above which the agency considers associated with
11 adverse neurodevelopmental effects in babies. The FDA, in its guidance documents for
12 inorganic arsenic and lead in baby food products has repeatedly acknowledged the dangers of
13 heavy metals to the neurodevelopment of infants.

14 Even low lead exposure can harm children’s health and development, specifically
15 the brain and nervous system. Neurological effects of lead exposure during early
16 childhood include learning disabilities, behavior difficulties, and lowered IQ.
17 Lead exposures also may be associated with immunological, cardiovascular,
18 renal, and reproductive and/or developmental effects...Because lead can
19 accumulate in the body, even low-level chronic exposure can be hazardous over
20 time...Even though no safe level of lead exposure has yet been identified for
21 children's health, the IRL serves as a useful benchmark in evaluating the potential
22 for adverse effects of dietary lead. In particular, FDA is focused on the potential
23 for neurodevelopmental effects from lead exposure, as review of the scientific
24 literature indicates that *such adverse effects of lead consistently occur at a blood
25 lead level associated with FDA’s IRL for children.* (emphasis added).

26 65. As one recent study observed, “[t]he implications of heavy metals with regards
27 to children’s health have been noted to be more severe compared to adults. The elements’
28 harmful consequences on children health include mental retardation, neurocognitive disorders,
behavioral disorders, respiratory problems, cancer and cardiovascular diseases. Much attention
should be given to heavy metals because of their high toxicity potential, widespread use, and
prevalence.” Children and, even more so, babies have higher exposure to metals compared to
adults because they consume more food in relation to their body weight and absorb metals more
readily than adults by 40 to 90%.

1 66. The mechanisms needed to metabolize and eliminate heavy metals are
2 comparatively undeveloped in childhood, with babies having weaker detoxifying mechanisms
3 and poorer immune systems than adults. For example, liver pathways that in adulthood
4 metabolize absorbed arsenic do not mature until mid-childhood; un-excreted arsenic thus
5 continues to circulate and is deposited in other organs. According to Linda McCauley, Dean of
6 the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental
7 health effects, “[n]o level of exposure to these [heavy] metals has been shown to be safe in
8 vulnerable infants.”

9 67. Thus, “the major windows of developmental vulnerability occur during infancy
10 and early childhood due to continuing brain development after birth.” In short, even small
11 amounts of exposure to Toxic Heavy Metals can have devastating health outcomes for babies
12 and children.

13 **VI. Exposure to Toxic Heavy Metals Has Been Consistently Associated with**
14 **Neurodevelopmental Harm, i.e., Autism and ADHD in Pediatric Populations**

15 68. It is well-known that exposure to Toxic Heavy Metals in early life can interfere
16 with neurodevelopment at exceedingly low levels of exposure. And, one of the ways in which
17 such interference with neurodevelopment can present in a child is in the form of the
18 neurodevelopmental disorders ASD and ADHD. As the U.S. Centers for Disease Control
19 observed in its 2020 Toxicological Profile for Lead, at just ≤ 10 $\mu\text{g/dL}$: “The following
20 neurobehavioral effects in children have been associated with [lead]: “Altered mood and
21 behaviors that may contribute to learning deficits, including *attention deficits*, *hyperactivity*,
22 *autistic behaviors*, conduct disorders, and delinquency.” (emphasis added). Likewise, the NIH
23 states: “prenatal and early childhood exposure to heavy metals...may be linked to autism
24 spectrum disorder.”

25 69. Such conclusions have likewise been reached by a consortium of the country’s
26 leading epidemiologists, pediatricians, and medical groups, noting that Toxic Heavy Metals
27 such as lead and mercury are “prime examples of toxic chemicals that can contribute to
28 learning, behavioral, or intellectual impairment, as well as specific neurodevelopmental

1 disorders such as ADHD or autism spectrum disorder.”

2 70. Multiple studies, reviews, and meta-analyses conducted throughout various parts
3 of the world over the last decade have consistently observed that early life exposure to heavy
4 metals can cause brain injury and, specifically, brain injury which manifests as ASD.

5 71. For example, four meta-analyses published in 2014, 2017, 2019 and 2020,
6 respectively, observed consistent associations between exposure to arsenic, cadmium, and
7 mercury and ASD in children; with the authors in all three studies recommending – based on
8 the data – that exposure to such metals in children be reduced as much as possible, and one of
9 the study authors specifically concluding that “Results of the current meta-analysis revealed that
10 mercury is an important causal factor in the etiology of ASD.”

11 72. In a recent 2017 NIH-funded prospective observational study, the authors
12 examined the risk of ASD outcome in twins based on their respective body burden of lead. The
13 study concluded in no uncertain terms that “prenatal and early childhood disruption (excess or
14 deficiency) of multiple metals during critical developmental windows is associated with ASD,
15 and suggests a role for elemental dysregulation in the etiology of ASD.”

16 73. Similarly, a large, prospective study from 2016 in Korean school children
17 observed that low levels of lead exposure in early life are associated with autism, the authors
18 specifically concluding: “even low blood lead concentrations...are associated with more autistic
19 behaviors... underscoring the need for continued efforts to reduce lead exposure.”

20 74. Studies have repeatedly observed strong associations between exposure to
21 cadmium and aluminum and neurodevelopmental disorders such as ASD, as observed by a
22 recent study: “Environmental exposure to...cadmium (Cd)... and aluminum (Al) has been
23 associated with neurodevelopmental disorders including autism spectrum disorder (ASD).” For
24 example, a study from 2014 evaluated the body burden of lead, cadmium, and arsenic in
25 children with autism compared to controls and noted that, in addition to lead and arsenic, “our
26 study demonstrated elevation in the levels of...cadmium...in a child with autism,” while an
27 earlier study noted that “autism may be associated with significant alterations of some rare
28 element concentrations, including Cd...” Such results have been confirmed by meta-analyses

1 which “show *significant associations* between ASD and the metals Al [and] Cd.” And, such
2 earlier data is further supported by recent research, with a 2023 systematic review and meta-
3 analysis concluding that “compared with the healthy control group, the ASD group had higher
4 concentrations of Cd, Pb, arsenic, and Hg. These 4 heavy metals play different roles in the
5 occurrence and progression of ASD.”

6 75. Repeated associations between early life Toxic Heavy Metal exposure and ASD
7 have also been observed during the pre-natal timeframe, lending further strength to the findings
8 of post-natal studies. For example, in a 2021 study by Skogheim and colleagues, the authors
9 prospectively assessed the relationship between pre-natal metal exposure in various biomarkers
10 and autism risk. The study concluded that “[r]esults from the present study show several
11 associations between levels of metals and elements during gestation and ASD and ADHD in
12 children. The most notable ones involved arsenic...mercury...and lead. Our results suggest that
13 even population levels of these compounds may have negative impacts on neurodevelopment.”

14 76. Similarly, in a study by the research group assessing the New Hampshire Birth
15 Cohort, the authors evaluated the neurotoxic effects of heavy metals during various stages of
16 pregnancy and concluded: “Our results support the hypothesis that exposure to...As in mid to
17 late pregnancy may be neurodevelopmentally harmful.”

18 77. Such results have been replicated in studies throughout the world, including
19 China, Korea, the U.S., Europe, and Egypt, implicating arsenic, mercury, and lead in pediatric
20 diagnoses of autism and autistic behaviors, with a 2018 Chinese study concluding: “[t]he results
21 of this study are consistent with numerous previous studies, supporting an important role for
22 heavy metal exposure, particularly mercury, in the etiology of ASD.” Indeed, a 2015 Egyptian
23 study noted “[e]nvironmental exposure to these toxic heavy metals, *at key times in development*,
24 may play a *causal* role in autism.” (emphasis added).

25 78. Exposure to Toxic Heavy Metals, specifically lead, has also been repeatedly
26 associated with the development of ADHD in children, as demonstrated by numerous studies.

27 79. No fewer than four large meta-analyses, conducted in four different continents
28 (North America, South America, Europe and Asia), and some employing a cross-sectional

1 design, have observed a consistent association between various metals and ADHD in children.
2 Indeed, the authors of the meta-analysis from Spain noted that “the evidence from the studies
3 allowed us to establish that there is an association between lead and ADHD and that even *low*
4 *levels of lead raise the risk.*” (emphasis added).

5 80. The findings from the meta-analyses have been replicated in several Chinese
6 studies from 2006, 2014, and 2018, respectively. Notably, the authors of the 2014 Chinese
7 study observed that “[e]xposure to lead even at low levels correlates with attention-
8 deficit/hyperactivity disorder (ADHD). However, lead-contaminated environments are often
9 *contaminated with other heavy metals that could exacerbate lead-induced ADHD.*” (emphasis
10 added). This is particularly relevant—and disturbing—as children who consumed Defendants’
11 baby foods were repeatedly exposed to a cocktail of Toxic Heavy Metals that, synergistically,
12 further increased their risk of developing ADHD.

13 81. Moreover, studies have observed a dose-response relationship between exposure
14 to Toxic Heavy Metals and ADHD, as demonstrated by the 2016 Spanish study Donzelli, *et al.*
15 Another 2016 cross-sectional study from Spain was conducted on 261 children aged 6-9 to
16 examine the association between exposure to arsenic and ADHD. After adjusting for potential
17 confounders, the authors observed a dose-response relationship between urine arsenic levels and
18 inattention and impulsivity scores, concluding that “[urine arsenic] levels were associated with
19 impaired attention/cognitive function, *even at levels considered safe.* These results provide
20 additional evidence that postnatal arsenic exposure impairs neurological function in children.”
21 (emphasis added).

22 82. The fact that such results, and many more, have been observed in multiple
23 studies, conducted by different researchers, at different times, in different parts of the world, in
24 children of multiple ages, utilizing different study methods (prospective, case-control and cross-
25 sectional epidemiological analyses) and measuring a variety of end-points (including hair,
26 blood, and urine), strongly supports a causal relationship between exposure to Toxic Heavy
27 Metals and the development of ASD and ADHD in children.

28 **VII. Defendants’ Baby Foods Contain Toxic Heavy Metals Capable of Interfering with**

Early Neurodevelopment

83. As illustrated above, Toxic Heavy Metal exposure is capable of inflicting damage to the developing brain at extremely low doses. And, upon information and belief, Defendants manufactured and sold baby foods containing Toxic Heavy Metals that can, under certain circumstances (based upon the genetic susceptibilities, medical history, and other factors of the exposed child) interfere with a baby's neurodevelopment sufficient to cause conditions such as ASD and ADHD.

84. As an initial matter, the study commissioned by HBBF and discussed above specifically evaluated the propensity for arsenic exposure through consumption of infant rice cereal to impact early life neurodevelopment. Following analyses of the levels of arsenic exposure from consumption of infant rice cereal, the authors concluded "that high consumers of infant rice cereal (i.e., infants eating three servings per day) eating products currently on the U.S. market would have a daily arsenic intake of 0.35-0.67 $\mu\text{g/kg bw/day}$...per the Tsuji et al. (2015) lower-bound estimate for an RfD for the neurodevelopmental effects of arsenic (0.4 $\mu\text{g/kg bw/day}$), high consumers of infant rice cereal may also be at risk for this endpoint. Even in average consumers of infant rice cereal (i.e., one serving per day), our estimates of arsenic intakes (0.15 to 0.29 $\mu\text{g/kg bw/day}$) leave little room for exposures to arsenic from other sources." Thus, consumption of Defendants' baby foods, including but not limited to infant rice cereal and rice-based snack baby food products manufactured and sold by Defendants can expose babies to levels of arsenic above that associated with neurodevelopmental harm in the scientific literature.

85. Defendants manufactured and sold baby food products that, with just a couple of servings, are capable of exposing a baby to lead levels at or above the 2.2 $\mu\text{g/day}$ considered by the FDA to be associated with neurodevelopmental harm. Each source of lead exposure is cumulative—making any detectable amount of Toxic Heavy Metal in baby food a contributing factor to potential neurodevelopmental harm.

VIII. Defendants Knowingly Sold Baby Foods Containing Toxic Heavy Metals and Knew or Should Have Known of the Risks of Such Exposures in Children and Thus

Breeched their Duty of Care in Selling Contaminated Baby Foods

86. During the time that Defendants manufactured and sold baby foods in the United States, the weight of evidence showed that Defendants' baby foods exposed babies and children to Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through any means.

87. As discussed above, both independent testing, the Defendants' internal evaluations of their baby foods, and the Defendants' representations and disclosures to Congress and the FDA reveal the presence of Toxic Heavy Metals in Defendants' products. As such, Defendants knew or should have known that their baby foods contain Toxic Heavy Metals with an attendant risk of causing neurodevelopmental harm.

88. Indeed, independent testing performed in early 2019 demonstrated elevated amounts of such Toxic Heavy Metals in Baby Food products on the U.S. market, and the HBBF Report further confirmed such contamination of Defendants' baby foods. And, as the Congressional investigation found, the Defendants continued to sell their baby foods even after testing of both ingredients and finished products revealed the presence of Toxic Heavy Metals.

89. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—particularly as it relates to adverse effects on the neurodevelopment of children—have been well known for decades. Defendants, as manufacturers and sellers of baby foods, are held to the standard of experts and responsible for keeping abreast of the latest scientific developments related are held to the dangers of contaminants in their products. Defendants failed to take action to protect vulnerable children from exposure to the Toxic Heavy Metals in their foods and, thus, subjected them to the risk of brain injury which can manifest as neurodevelopmental disorders such as ASD, ADHD, and related *sequelae*.

90. To be clear, the Defendants are able to manufacture baby foods that do not pose such a dangerous risk to the health of infants and children by using alternative ingredients, not adding certain pre-mix minerals and vitamins high in Toxic Heavy Metals or sampling their ingredients from other sources. At the very least, Defendants were under a duty to warn unsuspecting parents of the presence of Toxic Heavy Metals in their Baby Foods.

IX. Defendants' Baby Food Products Were Defective Due to Insufficient Warnings, Manufacturing Defects, and/or Design Defects to the Extent the Baby Food Products Contained Detectable Levels of Toxic Heavy Metal

91. All of Defendants' baby food products that contained detectable levels of Toxic Heavy Metals (or constituted finished products wherein the ingredients contained detectable levels of Toxic Heavy Metals), assuming state of the art analytical testing, were defective as it relates to warnings because no Defendant has ever warned about the presence of Toxic Heavy Metals in their baby foods. Because discovery is ongoing, a complete list of Defendants' specific baby foods that contained detectable levels of Toxic Heavy Metals is not known at this time. Based on publicly available testing data, including data reported by HBBF and Congress, the vast majority of Defendants' products contain detectable levels of Toxic Heavy Metals in them, rendering them each defective as it relates to warnings.

92. Defendants' baby food products are also defective as manufactured, as they contain detectable Toxic Heavy Metals which are not supposed to be there, by design. Toxic Heavy Metals do not provide any nutritional or therapeutic value to infants or fully-grown humans. They are only poisonous to neurodevelopment. None of these baby food products, by design, should contain Toxic Heavy Metals in them and, thus, to the extent the products contain detectable levels of Toxic Heavy Metals in them, those are manufacturing defects. Based on publicly available data, most of Defendants' baby food products contain some detectable levels of Toxic Heavy Metals in them.

93. If Defendants specifically designed their baby food products to contain Toxic Heavy Metals, meaning their presence was not the product of a manufacturing defect, then the products were defective by design. Toxic Heavy Metals should not be present in foods that are being consumed by infants and products should be designed to not have detectable levels of toxic heavy metal in them. Such designs are easily accomplished, by only using ingredients that contain non-detectable levels of Toxic Heavy Metals and by testing finished products, before release, to ensure they do not contain Toxic Heavy Metals within them. This is possible because there are examples of Defendants' finished products not containing detectable levels of

1 Toxic Heavy Metals—even if, for that same products, there are instances where they did. Thus,
2 Defendants were able to design baby food products to not contain detectable levels of toxic
3 heavy metals, and to the extent that each Defendants’ design contemplated there being
4 detectable levels of Toxic Heavy Metals in baby food, the design, itself, was defective.

5 94. Whether the Defendants’ products were defective due to inadequate warnings,
6 manufacturing errors, or by design, the existing publicly available evidence indicates that
7 consumption of Defendants’ baby food products exposed Plaintiff to Toxic Heavy Metals, and
8 that Defendants’ baby food products contributed to Plaintiff’s Toxic Heavy Metal burden
9 during a critical period of infant neurodevelopment. Plaintiff, thus, alleges that this cumulative
10 exposure from Defendants’ products to Toxic Heavy Metals, substantially contributed to
11 causing neurodevelopmental harm that manifested as ASD. Moreover, Plaintiff alleges that had
12 these baby food products not been defective—by having sufficient warnings, being correctly
13 manufactured, and/or designed properly—Plaintiff would not have been exposed to levels of
14 Toxic Heavy Metals in Defendants’ baby food products that would have contributed to the
15 neurodevelopmental harm that manifested as ASD.

16 **X. Exemplary / Punitive Damages Allegations**

17 95. Defendants’ conduct as alleged herein was done with reckless disregard for
18 human life, oppression, and malice. Defendants’ conduct is particularly reprehensible given
19 that their toxic foods were directed at vulnerable babies—a population group far more
20 susceptible than adults to the neurotoxic dangers of heavy metals.

21 96. Defendants were fully aware of the safety risks of Contaminated Baby Foods,
22 particularly the dangerous potential of Toxic Heavy Metals on neurodevelopment in infants and
23 children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to
24 mislead consumers. Indeed, Defendants repeatedly market their baby foods as safe for
25 consumption and go so far as claiming that they adhere to “the strictest standards in the world;”
26 and provide “baby’s food full of nutrition while meeting standards strict enough for tiny
27 tummies,” as well as other statements and representations that hold out their baby foods as safe
28 for consumption by infants. Indeed, each Defendant falsely reassured

1 parents/guardians/caregivers that their baby foods would foster healthy neurodevelopment when
2 consumed even though they knew their baby foods exposed infants' developing brains to potent
3 neurotoxic heavy metals. In actual fact, as discussed above, Defendants routinely sold
4 Contaminated Baby Foods, regularly flouted their own internal limits of Toxic Heavy Metals
5 and failed to disclose to consumers that their products contained such dangerous contaminants.

6 97. This was not done by accident or through some justifiable negligence. Rather,
7 Defendants knew they could profit by convincing consumers that their baby foods were healthy
8 and safe for infants, and that full disclosure of presence and/or risks of the Toxic Heavy Metals
9 present in the baby foods would limit the amount of money Defendants would make selling the
10 products. Defendants' object was accomplished not only through a misleading label, but
11 through a comprehensive scheme of selective misleading research and testing, failure to test,
12 false advertising, and deceptive omissions as more fully alleged throughout this Complaint.
13 Parents/guardians/caregivers were denied the right to make an informed decision about whether
14 to purchase Defendants' baby food for their babies without knowing the full risks attendant to
15 that use. Such conduct was done with conscious disregard of Plaintiff's welfare and rights.

16 **PLAINTIFF'S USE AND INJURY**

17 98. Plaintiff was diagnosed with ASD at approximately 2 years of age.

18 99. Plaintiff started consuming Baby Food products manufactured and/or sold by the
19 Defendants in approximately 2020 and consumed Defendants' Baby Food products at various
20 times through 2020.

21 100. Upon information and belief, the Baby Food products manufactured/marketed by
22 Defendants and consumed by Plaintiff were all contaminated with substantial quantities of
23 Toxic Heavy Metals.

24 101. Upon information and belief, as a direct and proximate result of consuming
25 Defendants' Baby Foods, Plaintiff was exposed to substantial quantities of Toxic Heavy Metals.

26 102. As a direct and proximate result of consuming Defendants' Baby Foods and the
27 exposure to the Toxic Heavy Metals therein – Plaintiff suffered brain injury which manifested
28 as ASD and related *sequelae*.

103. Based on prevailing scientific evidence, exposure to the Toxic Heavy Metals at the levels contained in Defendants' Baby Foods can cause brain injury which can manifest as the neurodevelopmental disorder ASD and related *sequelae* in humans.

104. Had any Defendant warned Plaintiff's parents that Defendants' Baby Foods could lead to exposure to Toxic Heavy Metals or, in turn, brain injury, Plaintiff would not have consumed the Baby Foods.

105. Plaintiff alleges that as a direct and proximate result of Plaintiff's consumption of Baby Foods supplied and distributed by Defendants, Plaintiff suffered significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to brain injury which manifested as ASD and related *sequelae*.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

106. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

107. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and promoting baby foods, which are defective and unreasonably dangerous to consumers, including Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of baby foods in the form of the presence of Toxic Heavy Metals. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold baby foods and aimed at a consumer market.

108. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their Contaminated Baby Foods, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn about the presence of and risks associated with exposure to Toxic Heavy Metals from the consumption of Contaminated Baby Foods.

1 109. At all relevant times, Defendants had a duty to properly test, develop, design,
2 manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply,
3 provide proper warnings, and take such steps as necessary to ensure their Contaminated Baby
4 Foods did not cause users and consumers to suffer from unreasonable and dangerous risks.
5 Defendants had a continuing duty to warn Plaintiff of dangers associated with exposure to
6 Toxic Heavy Metals from consumption of the Contaminated Baby Foods. Defendants, as a
7 manufacturer, seller, or distributor of food, are held to the knowledge of an expert in the field.

8 110. At the time of manufacture, Defendants could have provided the warnings or
9 instructions regarding the full and complete risks of exposure to Toxic Heavy Metals in the
10 Contaminated Baby Foods because they knew or should have known of the unreasonable risks
11 of harm associated with the use of and/or exposure to such toxins.

12 111. At all relevant times, Defendants failed and deliberately refused to investigate,
13 study, test, or promote the safety or to minimize the dangers to users and consumers of their
14 product and to those who would foreseeably use or be harmed by exposure to the Toxic Heavy
15 Metals in Defendants' Baby Foods.

16 112. Even though Defendants knew or should have known that the presence of Toxic
17 Heavy Metals in Contaminated Baby Foods posed a risk of harm, they failed to exercise
18 reasonable care to warn of the dangerous risks associated with use and exposure to the toxins in
19 the products. The neurotoxic characteristic of Toxic Heavy Metals contained in Defendants'
20 Contaminated Baby Foods, as described above, were known to Defendants, or scientifically
21 knowable to Defendants through appropriate research and testing by known methods, at the
22 time they distributed, supplied, or sold the products, and were not known to end users and
23 consumers, such as Plaintiff. The product warnings for Contaminated Baby Foods in effect
24 during the time period Plaintiff consumed those foods were inadequate, both substantively and
25 graphically, to alert consumers to the presence of and health risks associated with exposure to
26 the Toxic Heavy Metals from Contaminated Baby Food consumption.

27 113. At all relevant times, Defendants' Contaminated Baby Foods reached the
28 intended consumers, handlers, and users or other persons coming into contact with these

1 products, including Plaintiff, without substantial change in their condition as manufactured,
2 sold, distributed, labeled, and marketed by Defendants.

3 114. Plaintiff was exposed to the Toxic Heavy Metals in Defendants' Contaminated
4 Baby Foods without knowledge of the potential for such exposure to Toxic Heavy Metals from
5 consumption of the products and the dangerous characteristics of the toxins.

6 115. At all relevant times, Plaintiff was exposed to the Toxic Heavy Metals in the
7 Defendants' Contaminated Baby Foods while consuming the foods for their intended or
8 reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

9 116. Plaintiff could not have reasonably discovered the defects and risks associated
10 with exposure to the Toxic Heavy Metals in the Contaminated Baby Foods prior to or at the
11 time of Plaintiff consuming those foods. Plaintiff relied upon the skill, superior knowledge, and
12 judgment of Defendants to know about and disclose serious health risks associated with
13 exposure to the toxins in Defendants' products.

14 117. The information that Defendants did provide or communicate failed to contain
15 relevant warnings, hazards, and precautions that would have enabled consumers such as
16 Plaintiff to avoid consuming the products and, in turn, exposure to the Toxic Heavy Metals.
17 Instead, Defendants disseminated information that was inaccurate, false, and misleading, and
18 which failed to communicate accurately or adequately the comparative severity, duration, and
19 extent of the risk of injuries with use of and/or exposure to the Toxic Heavy Metals in the
20 Contaminated Baby Foods; continued to aggressively promote the safety of their products, even
21 after they knew or should have known of the unreasonable risks from use or exposure; and
22 concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion,
23 any information or research about the risks and dangers of exposure to Toxic Heavy Metals
24 from consumption of Contaminated Baby Foods.

25 118. This alleged failure to warn is not limited to the information contained on
26 Contaminated Baby Foods labeling. The Defendants were able, in accord with federal law, to
27 comply with relevant state law by disclosing the known risks associated with exposure to Heavy
28 Metals in Contaminated Baby Foods through other non-labeling mediums, i.e., promotion,

1 advertisements, public service announcements, and/or public information sources. But the
2 Defendants did not disclose these known risks through any medium. The ability to provide such
3 warnings is not prohibited by any federal law.

4 119. Furthermore, Defendants possess a First Amendment Right to make truthful
5 statements about the products they sell, and no law could lawfully restrict that constitutional
6 right. This included making statements about the presence of and risks associated with Toxic
7 Heavy Metals in Contaminated Baby Foods.

8 120. Had Defendants provided adequate warnings and instructions and properly
9 disclosed and disseminated the risks associated with exposure to the toxins in their
10 Contaminated Baby Foods, Plaintiff could have avoided the risk of developing injuries and
11 could have obtained or used alternative products. However, as a result of Defendants'
12 concealment of the dangers posed by the Toxic Heavy Metals in their Contaminated Baby
13 Foods, Plaintiff could not have averted their exposures.

14 121. Defendants' conduct, as described above, was reckless. Defendants risked the
15 lives of babies and children, including Plaintiff, with knowledge of the safety problems
16 associated with Contaminated Baby Foods, and suppressed this knowledge from the general
17 public. Defendants made conscious decisions not to warn or inform the unsuspecting public.

18 122. The Defendants' lack of adequate warnings and instructions accompanying their
19 Contaminated Baby Foods caused Plaintiff's injuries.

20 123. As a direct and proximate result of the Defendants' failure to provide an
21 adequate warning of the risks of exposure to the Toxic Heavy Metals in their Contaminated
22 Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering,
23 disability, impairment, loss of enjoyment of life, economic loss and damages including, but not
24 limited to past and future medical expenses, lost income, and other damages.

25 124. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
26 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
27 all such other and further relief as this Court deems just and proper.

28 **COUNT II: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

1 125. Plaintiff incorporates by reference each allegation set forth in preceding
2 paragraphs as if fully stated herein.

3 126. At all times herein mentioned, Defendants designed, manufactured, tested,
4 marketed, sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiff.

5 127. At all relevant times, the Contaminated Baby Foods consumed by Plaintiff were
6 expected to and did reach Plaintiff without a substantial change in their condition as
7 manufactured, handled, distributed, and sold by Defendants.

8 128. At all relevant times, the Contaminated Baby Foods consumed by Plaintiff were
9 used in a manner that was foreseeable and intended by Defendants.

10 129. The Contaminated Baby Foods consumed by Plaintiff were not reasonably safe
11 for their intended use and were defective with respect to their manufacture, as described herein,
12 in that Defendants deviated materially from their design and manufacturing specifications
13 and/or such design and manufacture posed an unreasonable risk of harm to Plaintiff.¹ Baby
14 food should not, by design, contain any detectable levels of Toxic Heavy Metals in them. Thus,
15 Defendants' Contaminated Baby Foods contain manufacturing defects.

16 130. The Defendants' Contaminated Baby Foods contained Toxic Heavy Metals
17 because, while in the control and possession of Defendants, they manufactured ingredients and
18 used manufacturing processes that result in the finished product being contaminated with Toxic
19 Heavy Metals. Had Defendants properly manufactured (directly or through co-manufacturers)
20 the baby foods, they would not have contained detectable levels of Toxic Heavy Metals in them
21 and, thus, would not have contained a manufacturing defect.

22 131. Nothing under federal law limited or restricted Defendants from taking action to
23 reduce or eliminate the Toxic Heavy Metals from being present in their baby foods.

24 132. This manufacturing defect caused Plaintiff to be exposed to Toxic Heavy Metals
25 through ingestion of the Contaminated Baby Foods which, in turn, caused neurodevelopmental
26 harm that manifested as ASD.

27 ¹ If, through discovery and further litigation, it is discovered that Defendants' baby food
28 products contained detectable levels of Toxic Heavy Metals by design, then Plaintiff will
pursue a design defect claim (Count III) in the alternative.

133. The exposure to the Toxic Heavy Metals in the Contaminated Baby Foods creates risks to the health and safety of babies that are far more significant than the risks posed by non- Contaminated Baby Food products, and which far outweigh the utility of the Contaminated Baby Foods products because of Defendants' manufacturing defects.

134. Defendants have intentionally and recklessly manufactured the Contaminated Baby Foods with wanton and willful disregard for the rights and health of Plaintiff, and with malice, placing their economic interests above the health and safety of Plaintiff.

135. As a direct and proximate result of the Defendants' defective manufacture of the Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

136. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

137. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

138. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiff. These actions were under the ultimate control and supervision of Defendants.

139. At all relevant times, Defendants' Baby Food products were designed and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use or consumption by infants and babies, including Plaintiff.

140. Defendants' Contaminated Baby Food products as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they were placed into the stream of commerce, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate.

1 141. Defendants' Contaminated Baby Food products, as researched, tested,
2 developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed
3 by Defendants were defective in design and formulation in that, when they left the hands of
4 Defendants, the foreseeable risks exceeded the alleged benefits associated with their design and
5 formulation.

6 142. At all relevant times, the Contaminated Baby Food products consumed by
7 Plaintiff were expected to and did reach Plaintiff without a substantial change in its condition as
8 designed, manufactured, handled, distributed, and sold by Defendants.

9 143. At all relevant times, Defendants knew or had reason to know that their
10 Contaminated Baby Food products were defective and were inherently dangerous and unsafe
11 when used in the manner instructed and provided by Defendants.

12 144. Therefore, at all relevant times, Defendants' Baby Food products, as researched,
13 tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed,
14 sold and marketed by Defendants were defective in design and formulation, in one or more of
15 the following ways:

16 A. When placed in the stream of commerce, Defendants' Contaminated
17 Baby Food products were unreasonably dangerous in that they contained Toxic Heavy Metals
18 that posed a risk of causing interference with neurodevelopment in babies that manifests as the
19 neurodevelopmental disorders ASD, ADHD and related *sequelae* when used in a reasonably
20 anticipated manner;

21 B. When placed in the stream of commerce, Defendants' designed
22 Contaminated Baby Food products to contain unreasonably dangerous design defects and were
23 not reasonably safe when used in a reasonably anticipated or intended manner;

24 C. Defendants, by design, did not sufficiently test, investigate, or study their
25 Contaminated Baby Food products;

26 D. Exposure to the Toxic Heavy Metals in Defendants' Contaminated Baby
27 Food products present a risk of harmful effects that outweigh any potential utility stemming
28 from their use;

1 E. Defendants, by design, did not conduct adequate post-marketing
2 surveillance of their Contaminated Baby Food products which would have alerted the public to
3 risks; and

4 F. Defendants could have employed safer alternative designs and
5 formulations for Contaminated Baby Foods, such as ensuring the baby food did not have any
6 detectable level of Toxic Heavy Metals.

7 145. Plaintiff consumed Defendants' Contaminated Baby Food products in an
8 intended or reasonably foreseeable manner without knowledge of their dangerous
9 characteristics.

10 146. Defendants' Contaminated Baby Food products were and are more dangerous
11 than alternative products, and Defendants could have designed their Contaminated Baby Food
12 products to avoid harm to children. Indeed, at the time Defendants designed the Contaminated
13 Baby Food products, the state of the industry's scientific knowledge was such that a less risky
14 design or formulation was attainable.

15 147. At the time the Contaminated Baby Food products left Defendants' control, there
16 was a practical, technically feasible, and safer alternative design that would have prevented the
17 harm without substantially impairing the reasonably anticipated or intended function of
18 Defendants' Contaminated Baby Foods.

19 148. Defendants intentionally and recklessly defectively designed the Contaminated
20 Baby Foods with wanton and willful disregard for the rights and health of Plaintiff, and with
21 malice, placing their economic interests above the health and safety of Plaintiff.

22 149. The design defects in Defendants' Contaminated Baby Foods were substantial
23 factors in causing Plaintiff's injuries.

24 150. As a direct and proximate result of the Defendants' defective design of the
25 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
26 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages
27 including, but not limited to medical expenses, lost income, and other damages.

28 151. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in

1 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
2 all such other and further relief as this Court deems just and proper.

3 **COUNT IV: NEGLIGENCE – FAILURE TO WARN**

4 152. Plaintiff incorporates by reference each allegation set forth in preceding
5 paragraphs as if fully stated herein.

6 153. At all relevant times, Defendants engaged in the business of testing, developing,
7 designing, manufacturing, marketing, selling, distributing, and promoting baby foods.
8 Defendants knew, or, by the exercise of reasonable care, should have known that their
9 Contaminated Baby Foods are not accompanied with adequate warnings concerning the
10 dangerous characteristics of exposure to Toxic Heavy Metals from consumption. These actions
11 were under the ultimate control and supervision of Defendants.

12 154. Defendants researched, developed, designed, tested, manufactured, inspected,
13 labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of
14 commerce their Contaminated Baby Foods, and in the course of same, directly advertised or
15 marketed the products to consumers and end users, including Plaintiff, and therefore had a duty
16 to warn of the risks associated with the presence of and exposure to Toxic Heavy Metals from
17 consumption of Contaminated Baby Foods.

18 155. At all relevant times, Defendants had a duty to properly test, develop, design,
19 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide
20 proper warnings, and take such steps as necessary to ensure their Contaminated Baby Foods did
21 not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants
22 had a continuing duty to warn Plaintiff of dangers associated with the presence of and exposure
23 to Toxic Heavy Metals from consumption of Contaminated Baby Foods. Defendants, as a
24 manufacturer, seller, or distributor of food products, are held to the knowledge of an expert in
25 the field.

26 156. At the time of manufacture, Defendants could have provided warnings regarding
27 the presence of and risks of exposure to Toxic Heavy Metals from consumption of
28 Contaminated Baby Foods because they knew or should have known exposure to Toxic Heavy

1 Metals from consumption of Contaminated Baby Foods was dangerous, harmful and injurious
2 when the Contaminated Baby Foods were consumed by Plaintiff in a reasonably foreseeable
3 manner.

4 157. At all relevant times, Defendants failed and deliberately refused to investigate,
5 study, test, or promote the safety or to minimize the dangers to users and consumers of their
6 products and to those who would foreseeably use or be harmed by Defendants' Contaminated
7 Baby Foods.

8 158. Defendants knew or should have known that exposure to Toxic Heavy Metals
9 from consumption of Contaminated Baby Foods posed a risk of harm, but failed to exercise
10 reasonable care to warn of the dangerous risks associated with use and exposure to the toxins in
11 the products. The dangerous propensities of exposure to Toxic Heavy Metals from consumption
12 of the Contaminated Baby Foods, as described above, were known to Defendants, or
13 scientifically knowable to Defendants through appropriate research and testing by known
14 methods, at the time they distributed, supplied, or sold the products, and were not known to end
15 users and consumers, such as Plaintiff.

16 159. At all relevant times, Plaintiff was exposed to Toxic Heavy Metals through
17 consumption of the Contaminated Baby Foods while using the products for their intended or
18 reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

19 160. Defendants knew or should have known that the non-extant warnings
20 disseminated with their Contaminated Baby Foods were inadequate, failed to communicate
21 adequate information on the presence of and dangers of exposure to toxins contained therein,
22 and failed to communicate warnings and instructions that were appropriate and adequate to
23 render the products safe for their ordinary, intended and reasonably foreseeable uses.

24 161. The information that Defendants did provide or communicate failed to contain
25 relevant warnings, hazards, and precautions that would have enabled consumers such as
26 Plaintiff to avoid using the product and, in turn, prevented exposure to the Toxic Heavy Metals
27 contained therein. Instead, Defendants disseminated information that was inaccurate, false, and
28 misleading, and which failed to communicate accurately or adequately the comparative severity,

1 duration, and extent of the risk of injuries with use of and/or exposure to the Toxic Heavy
2 Metals in the Contaminated Baby Foods; continued to aggressively promote the efficacy of their
3 products, even after they knew or should have known of the unreasonable risks from use or
4 exposure to the toxins contained therein; and concealed, downplayed, or otherwise suppressed,
5 through aggressive marketing and promotion, any information or research about the risks and
6 dangers of exposure to Toxic Heavy Metals from consumption of the Contaminated Baby
7 Foods.

8 162. A reasonable company under the same or similar circumstance would have
9 warned and instructed of the dangers of exposure to Toxic Heavy Metals from consumption of
10 Contaminated Baby Foods.

11 163. This alleged failure to warn is not limited to the information contained on the
12 labeling of Defendants' Contaminated Baby Foods. Defendants were able, in accord with
13 federal law, to comply with relevant state law by disclosing the known risks associated with
14 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods through other
15 non-labeling mediums, i.e., promotion, advertisements, public service announcements, and/or
16 public information sources. But the Defendants did not disclose these known risks through any
17 medium.

18 164. Furthermore, Defendants possess a First Amendment Right to make truthful
19 statements about the products they sell, and no law could lawfully restrict that constitutional
20 right.

21 165. Had Defendants provided adequate warnings and instructions and properly
22 disclosed and disseminated the risks associated with the presence of and exposure to Toxic
23 Heavy Metals in the Contaminated Baby Foods, Plaintiff could have avoided the risk of
24 developing injuries and could have obtained or used alternative products. However, as a result
25 of Defendants' concealment of the dangers posed by their Contaminated Baby Foods, Plaintiff
26 could not have averted their injuries.

27 166. Defendants' conduct, as described above, was reckless. Defendants risked the
28 lives of consumers and users of their products, including Plaintiff, with knowledge of the safety

1 problems associated with Contaminated Baby Foods, and suppressed this knowledge from the
2 general public. Defendants made conscious decisions not to warn or inform the unsuspecting
3 public.

4 167. The Defendants' lack of adequate warnings and instructions accompanying their
5 Contaminated Baby Foods were a substantial factor in causing Plaintiff's injuries.

6 168. As a direct and proximate result of the Defendants' failure to provide an
7 adequate warning of the risks of exposure to Toxic Heavy Metals from consumption of
8 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
9 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages
10 including, but not limited to past and future medical expenses, lost income, and other damages.

11 169. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
12 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
13 all such other and further relief as this Court deems just and proper.

14 **COUNT V: NEGLIGENCE – MANUFACTURING**

15 170. Plaintiff incorporates by reference each allegation set forth in preceding
16 paragraphs as if fully stated herein.

17 171. At all relevant times, the Defendants manufactured, tested, marketed, sold, and
18 distributed the Contaminated Baby Foods that Plaintiff consumed.

19 172. The Defendants had a duty to exercise reasonable care, in the manufacturing,
20 testing, marketing, sale, and distribution of baby foods.

21 173. The Defendants knew or, by the exercise of reasonable care, should have known,
22 that exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods rendered
23 the foods carelessly manufactured, dangerous, harmful and injurious when used by Plaintiff in a
24 reasonably foreseeable manner.

25 174. The Defendants knew or, by the exercise of reasonable care, should have known,
26 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of
27 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods.

28 175. Without limitation, examples of the manner in which Defendants breached their

1 duty to exercise reasonable care in manufacturing Contaminated Baby Foods, included:

2 A. Failure to adequately inspect/test the Contaminated Baby Foods, and
3 their ingredients, during and after the manufacturing process;

4 B. Failure to implement procedures that would reduce or eliminate Toxic
5 Heavy Metals in baby foods;

6 C. Failure to investigate suppliers and ingredient sources to reduce and
7 eliminate the risk of ingredients containing Toxic Heavy Metals; and

8 D. Failure to avoid using ingredients free from, or which contain far less,
9 Toxic Heavy Metals to manufacture baby food.

10 176. A reasonable manufacturer under the same or similar circumstances would have
11 implemented appropriate manufacturing procedures to better ensure the quality and safety of
12 their product.

13 177. Plaintiff was harmed directly and proximately by the Defendants' failure to use
14 reasonable care in the manufacture of their Contaminated Baby Foods. Such harm includes
15 exposure to Toxic Heavy Metals, which can cause or contribute to interference with early
16 neurodevelopment which manifests as ASD and related *sequelae*.

17 178. Defendants' improper manufacturing of Baby Foods was willful, wanton,
18 malicious, and conducted with reckless disregard for the health and safety of users of the
19 Contaminated Baby Foods, including Plaintiff.

20 179. The defects in Defendants' Contaminated Baby Foods were substantial factors in
21 causing Plaintiff's injuries.

22 180. As a direct and proximate result of the Defendants' improper manufacturing of
23 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
24 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages
25 including, but not limited to past and future medical expenses, lost income, and other damages.

26 181. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
27 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
28 all such other and further relief as this Court deems just and proper.

COUNT VI: NEGLIGENCE – PRODUCT DESIGN

182. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

183. Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Contaminated Baby Foods.

184. The Defendants owed a duty to all reasonably foreseeable users to design a safe product.

185. The Defendants breached their duty by failing to use reasonable care in the design of Contaminated Baby Foods because the products exposed babies to Toxic Heavy Metals.

186. The Defendants breached their duty by failing to use reasonable care in the design of Contaminated Baby Foods by negligently designing the foods with ingredients and/or components contaminated with Toxic Heavy Metals.

187. The Defendants breached their duty by failing to use reasonable care in the design of Contaminated Baby Foods by negligently designing and formulation, in one or more of the following ways:

A. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;

B. When placed in the stream of commerce, Defendants' Contaminated Baby Foods were unreasonably dangerous in that they were hazardous and posed a risk of neurodevelopmental disorders and other serious illnesses when used in a reasonably anticipated manner;

C. When placed in the stream of commerce, Defendants' Contaminated Baby Foods contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

D. Defendants did not sufficiently test, investigate, or study their

1 Contaminated Baby Foods and, specifically, the content of Toxic Heavy Metals in the
2 ingredients used to manufacture the foods and/or the finished products;

3 E. Defendants did not sufficiently test, investigate, or study their
4 Contaminated Baby Foods and, specifically, the ability for those foods to expose babies to
5 Toxic Heavy Metals; and

6 F. Exposure to the Toxic Heavy Metals in Contaminated Baby Foods
7 presents a risk of harmful effects that outweigh any potential utility stemming from the use of
8 the products;

9 188. Defendants knew or should have known at the time of marketing Contaminated
10 Baby Foods that exposure to Toxic Heavy Metals contained in the Baby Foods could result in
11 interference with early neurodevelopment that that manifests as ASD, ADHD and other severe
12 illnesses and injuries.

13 189. Defendants, by design, did not conduct adequate post-marketing surveillance of
14 their Contaminated Baby Foods.

15 190. Defendants could have employed safer alternative designs and formulations. For
16 example, the Defendants could have avoided use of certain ingredients contaminated with Toxic
17 Heavy Metals, avoided using pre-mix vitamins contaminated with Toxic Heavy Metals, and/or
18 sampled their ingredients from other sources.

19 191. The Defendants breached their duty by failing to use reasonable care by failing
20 to use cost effective, reasonably feasible alternative designs. There was a practical, technically
21 feasible, and safer alternative design that would have prevented the harm without substantially
22 impairing the reasonably anticipated or intended function of Defendants' Contaminated Baby
23 Foods.

24 192. A reasonable company under the same or similar circumstances would have
25 designed a safer product.

26 193. Plaintiff was harmed directly and proximately by the Defendants' failure to use
27 reasonable care in the design of their Contaminated Baby Foods. Such harm includes exposure
28 to Toxic Heavy Metals, which can cause or contribute to interference with neurodevelopment

1 that manifests as ASD and related *sequelae*.

2 194. Defendants' defective design of Contaminated Baby Foods was willful, wanton,
3 malicious, and conducted with reckless disregard for the health and safety of consumers of the
4 Baby Foods, including Plaintiff.

5 195. The defects in Defendants' Contaminated Baby Foods were substantial factors in
6 causing Plaintiff's injuries.

7 196. As a direct and proximate result of the Defendants' negligent design of the
8 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
9 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages
10 including, but not limited to past and future medical expenses, lost income, and other damages.

11 197. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
12 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
13 all such other and further relief as this Court deems just and proper.

14 **COUNT VII: GENERAL NEGLIGENCE**

15 198. Plaintiff incorporates by reference each allegation set forth in preceding
16 paragraphs as if fully stated herein.

17 199. Plaintiff pleads claims for negligence under all theories that may be actionable
18 under any applicable state laws.

19 200. Defendants owed Plaintiff a duty to act with reasonable care.

20 A. Defendants owed a duty because they distributed and promoted their
21 products as safe for children to consume.

22 B. Defendants owed a duty because their conduct created a risk of harm to
23 Plaintiff and caused Plaintiff actual harm.

24 C. Defendants owed a duty because the risk of harm to Plaintiff was
25 embedded in, and an inherent component of, their negligent business practices.

26 D. Defendants owed a duty because they designed, manufactured,
27 controlled, distributed, and sold their products to Plaintiff.

28 201. Defendants breached their duty to Plaintiff.

1 202. Defendants' negligence includes, but is not limited to, their marketing,
2 designing, manufacturing, producing, supplying, inspecting, testing, selling and/or distributing
3 Contaminated Baby Foods in one or more of the following respects:

4 A. Failure to implement procedures that would reduce or eliminate Toxic
5 Heavy Metals in baby foods;

6 B. Failure to investigate suppliers and ingredient sources to reduce and
7 eliminate the risk of ingredients containing Toxic Heavy Metals; and

8 C. Failure to avoid using ingredients free from, or which contain far less,
9 Toxic Heavy Metals to manufacture baby food.

10 D. When placed in the stream of commerce, Defendants' Contaminated
11 Baby Foods were defective in design and formulation, and, consequently, dangerous to an
12 extent beyond that which an ordinary consumer would contemplate;

13 E. When placed in the stream of commerce, Defendants' Contaminated
14 Baby Foods were unreasonably dangerous in that they were hazardous and posed a risk of
15 neurodevelopmental disorders and other serious illnesses when used in a reasonably anticipated
16 manner;

17 F. When placed in the stream of commerce, Defendants' Contaminated
18 Baby Foods contained unreasonably dangerous design defects and were not reasonably safe
19 when used in a reasonably anticipated or intended manner;

20 G. Defendants, by design, did not conduct adequate post-marketing
21 surveillance of their Contaminated Baby Food products which would have alerted the public to
22 risks; and

23 H. Defendants did not sufficiently test, investigate, or study their
24 Contaminated Baby Foods and, specifically, the ability for those foods to expose babies to
25 Toxic Heavy Metals;

26 I. Defendants could have employed safer alternative designs and
27 formulations for Contaminated Baby Foods, such as ensuring the baby food did not have any
28 detectable level of Toxic Heavy Metal.

1 J. Defendants did not sufficiently test, investigate, or study their
2 Contaminated Baby Foods and, specifically, the content of Toxic Heavy Metals in the
3 ingredients used to manufacture the foods and/or the finished products; and

4 K. Exposure to the Toxic Heavy Metals in Contaminated Baby Foods
5 presents a risk of harmful effects that outweigh any potential utility stemming from the use of
6 the products;

7 203. Defendants knew or should have known that their products contained detectable
8 levels of heavy metals that created an unreasonable risk of harm to children who consumed their
9 products.

10 204. At all relevant times, the Defendants knew or should have known that the
11 Products were unreasonably dangerous and defective when put to their reasonably anticipated
12 use.

13 205. As a proximate result of Defendants' negligence, Plaintiff has been injured,
14 sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of
15 life, economic loss, and damages including, but not limited to past and future medical expenses,
16 lost income, and other damages.

17 206. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
18 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
19 all such other and further relief as this Court deems just and proper.

20 **JURY TRIAL DEMAND**

21 207. Plaintiff demands a trial by jury on all the triable issues within this pleading.

22 **PRAYER FOR RELIEF**

23 208. **WHEREFORE**, Plaintiff requests that the Court enter judgment in Plaintiff's
24 favor and against the Defendants for:

- 25 a. actual or compensatory damages in such amount to be determined at trial and
26 as provided by applicable law;
27 b. exemplary and punitive damages sufficient to punish and deter the
28 Defendants and others from future wrongful practices;

- c. pre-judgment and post-judgment interest;
- d. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and
- e. any other relief the Court may deem just and proper.

DATED: December 17, 2024

Respectfully submitted,

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